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United States Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

03-005N
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Caroline Smith DeWaal

Re: *Listeria* Risk Assessment Technical Meeting–Notice of Availability and Public Meeting, Docket No. 03-005N
68 Fed. Reg. 6,109 (Feb. 6, 2003); 68 Fed. Reg. 8,737 (Feb. 25, 2003)

Introduction

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate the opportunity to comment on the Food Safety and Inspection Service's (FSIS) draft risk assessment for *Listeria* in ready-to-eat (RTE) meat and poultry plants. CSPI is a non-profit consumer-advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Listeria monocytogenes Remains A Significant Public-Health Threat

Four years ago *Listeria monocytogenes*-tainted deli meat from Sara Lee's Bil Mar plant sickened 100 people, killing 15 adults and causing six miscarriages and stillbirths. In response to the Sara Lee outbreak, FSIS vowed to develop aggressive strategies to cut the rate of listeriosis illnesses and deaths from RTE meat and poultry products in half by 2005.[1] Yet just a few

[1] Food Safety and Inspection Service and U.S. Department of Health and Human Services, Reducing the Risk of *Listeria monocytogenes*: Joint Response to the President, Jan. 2001.

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months ago we were in the midst of two large recalls as another large listeriosis outbreak from contaminated deli meat was linked to 53 illnesses, including eight deaths and three miscarriages or stillbirths.[2]

The recent outbreak and recalls serve as a harsh reminder, as we discuss this second draft risk assessment on RTE foods, that delays in risk-management decisionmaking can be devastating to consumers, as well as to the food industry and the government. Indeed, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) has admonished:

> Th[e] consideration of risk may not necessitate, in all situations, an in-depth quantitative risk assessment which requires extensive resources and time, particularly if it would delay timely protection of public health.[3]

This pathogen's high fatality and hospitalization rates, its ability to grow under refrigeration, and the lack of information on infectious dose all demand a prompt public-health response. Therefore, CSPI strongly urges FSIS not to allow this discussion of the new risk assessment model to deter or delay the promulgation of final *Listeria* testing regulations.

The Management Questions Failed To Address Non-Food Contact Surface Sampling

The draft risk assessment acknowledges that non-food contact surface (NFCS) sampling was not addressed in the management questions.[4] The failure to include NFCS sampling - as part of a comprehensive environmental sampling plan - limits the model's analysis of the

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[2] Centers for Disease Control and Prevention, Press Release, *Update: Listeriosis Outbreak Investigation*, Nov. 21, 2002.

[3] National Advisory Committee on Microbiological Criteria For Foods, Response to the Questions Posed by FSIS Regarding Performance Standards With Particular Reference to Ground Beef Products, Final Report, Oct. 8, 2002, p. 4.

[4] Food Safety and Inspection Service, Draft FSIS Risk Assessment for *Listeria* in Ready-to-eat Meat and Poultry Products, (Feb. 2003), p. 26 [hereinafter *FSIS Draft Risk Assessment*].

effectiveness of sampling as an intervention.

There is no apparent reason for the decision to exclude NFCS sampling, which is a key element of any *Listeria* control program. Indeed, FSIS's new *Listeria* Directive encourages NFCS sampling along with food-contact sampling and product testing, as part of a "science-based program addressing *L. monocytogenes* in product, food contact surfaces, and the environment."[5] Though the proposed rule would not mandate NFCS sampling, the model considered the effects of various intervention measures on the levels of *L. monocytogenes* contamination in finished RTE product and the subsequent risk of illness or death. Other interventions, such as the use of growth inhibitors, were considered, even though they would not be made mandatory as part of the agency's proposal.

The need for, and role of, NFCS sampling for *Listeria* spp. in RTE meat and poultry plants is well-established. Two large meat-industry surveys have documented the incidence of *Listeria* spp. on non-food contact surfaces. In one survey, sampling from more than 40 meat processors found *Listeria* spp. among drains, trenches, floors, exhaust hoods, cleaning aids and wash areas.[6] The other survey found that the incidence of *Listeria* spp. in floors, drains, cleaning aids, and wash areas was higher than the incidence on various food-contact surfaces.[7] Data from Cornell researchers presented to FSIS at the agency's May 2001 public meeting concur. Wiedmann's survey of RTE processing plants found that the incidence of *L. monocytogenes* was

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[5] Food Safety and Inspection Service, Microbial Sampling of Ready-to-Eat Products for the FSIS Verification Testing Program, Directive 10,240.3 (Dec. 9, 2002).

[6] Robert Gravani, Listeria *in Food-Processing Facilities, in Listeria*, Listeriosis, and Food Safety 664 (Elliot T. Ryser & Elmer H. Marth eds., 2nd ed. 1999) [hereinafter *Gravani*].

[7] *Gravani*, at 664-65.

much higher in drains and other NFCS than the incidence on food-contact surfaces.[8]

Not surprisingly, NFCS sampling is recommended in industry trade associations' and individual companies' *Listeria* control guidelines, including those of the National Food Processors Association, the North American Meat Processors, the National Meat Association, the Food Marketing Institute, the Central States Meat Association, South Eastern Meat Association, Southwest Meat Association, American Association of Meat Processors, and ConAgra.[9] Consumer groups agree. CSPI and several other consumer groups have endorsed NFCS sampling as an important element of a mandatory industry testing program.[10] We stated in our comment on the proposed rule:

> [A] broader testing regime is needed. . . . [S]ampling the plant environment and the final product is the most effective – indeed the only – way to verify that establishments are producing products under sanitary conditions and that they are meeting FSIS's pathogen reduction goals.[11]

The Inspector General has likewise concluded that FSIS needs to "require HACCP plans to include pathogen testing of product environment, contact surfaces, and final products,

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[8] Martin Wiedmann, Environmental *Listeria* testing and molecular subtyping to control *Listeria monocytogenes* in RTE food processing environments, Presentation at the Food Safety and Inspection Service Public Meeting on the Performance Standards for the Production of Processed Meat and Poultry Products (May 2001).

[9] National Food Processors Association, *Guidelines to Prevent Post Processing Contamination from* Listeria monocytogenes, April 1999; North American Meat Processors, *et al.*, *Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs): Ready-to-Eat (RTE) Products*, April 1999; ConAgra Refrigerated Prepared Foods, *ConAgra Refrigerated Prepared Foods' Current Strategy for* Listeria monocytogenes, May 19, 1999.

[10] Center for Science in the Public Interest, Petition for Regulatory Action to Require Microbial Testing By Industry for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Products (Jan. 13, 2000). CSPI was joined by the following members of the Safe Food Coalition: the American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, and Safe Tables Our Priority.

[11] Center for Science in the Public Interest, Comment on Proposed Rule Establishing Performance Standards for the Production of Processed Meat and Poultry Products (Sept. 10, 2001), p. 17. CSPI was joined by the following members of the Safe Food Coalition: the American Public Health Association, Consumer Federation of America, National Consumers League, and Safe Tables Our Priority.

particularly if a plant has a history of positive test results for microbes such as *Listeria.*"[12] Therefore, CSPI urges FSIS to revise its management questions to address the effectiveness of an environmental sampling program including both food-contact and non-food contact sampling.

Limitations to the Model's Forecasting Capability

In constructing the in-plant model, FSIS has limited the model's ability to provide accurate answers to the management questions. FSIS's decision to nearly halve the growth rate between processing and retail raises several questions: First, there is a significant lack of transparency in this decisionmaking. FSIS changed the growth rate based on raw data that have not been made publicly available.[13] Nor did the agency adequately explain its decision to depart from the studies it used to establish this growth rate in the earlier FDA/FSIS Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. This lack of transparency contravenes Codex's General Principles of Microbiological Risk Assessment, which demand that the "rationale, the logic of development, . . . limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review."[14]

Codex further instructs that data are to be used "to reduce uncertainty and to increase the

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[12] U.S. Department of Agriculture, Office of Inspector General, Food Safety Initiative: Meat and Poultry Products, *Food Safety and Inspection Service: Implementation of the Hazard Analysis and Critical Control Point System,* Report No. 24001-3-At (June 2000), p. 35.

[13] Since the publication of the draft risk assessment, the National Food Processors Association (NFPA) has placed in the docket for the risk assessment a pre-publication version of an article discussing certain findings from its retail sampling. However, the raw data on which the article was based were not placed in the docket. At the February 26, 2003, NFPA's Jenny Scott agreed that the raw data from its sampling would be made available to FSIS by the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland.

[14] Codex Alimentarius Commission, Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30) (1999), pp. 2-3 [hereinafter *Codex Risk Assessment Guidelines*].

reliability of the Risk Estimate."[15] But the use of the NFPA data has only increased the uncertainty associated with FSIS's in-plant model. For example, what do the raw data show regarding the prevalence and concentration of *L. monocytogenes* in manufacturer-packaged RTE deli meats, as opposed to RTE meats sliced at retail? These distinctions are critical, in that the in-plant model is designed to evaluate risks from contamination occurring at federally inspected establishments. In addition, the NFPA data appear to contradict available research on the post-production growth rate of *L. monocytogenes* in RTE meat and poultry products, as well as the agency's own data on the prevalence of this pathogen at processing. FSIS conceded in the Appendix to the new draft risk assessment:

> "[T]hese [NFPA] results suggest that fewer servings are contaminated at retail than at processing. Seemingly, instead of growth making the problem worse between processing and retail, these data imply that the situation is better at retail than at processing. This conclusion, however, is highly counterintuitive."[16]

Despite the increased uncertainty that has resulted from using NFPA's data, FSIS nevertheless cut the growth rate to 1.0 logs. This decision has a profound impact on the model's output (and the estimated illness-reduction rates derived therefrom). CSPI urges FSIS to reverse its decision to change the *L. monocytogenes* growth rate during distribution from 1.9 logs to 1.0 logs. And, if additional marketbasket sampling of RTE deli meats is needed to establish levels of *L. monocytogenes* attributable to contamination in a federally inspected facility, FSIS should discuss those data needs in the report, which can inform decisionmaking on the U.S. Department of Agriculture's research priorities.

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[15] *Codex Risk Assessment Guidelines,* at 4.

[16] *FSIS Draft Risk Assessment*, at 29.

The Risk Assessment Supports Increased Sampling & Testing Requirements

The risk assessment provides the scientific basis for FSIS to strengthen its proposed "4-2-1" testing scenario.[17] Modeling determined that the 4-2-1 scenario would allow only a "small reduction" in the levels of product contamination at retail, but an "increased frequency of food contact surface testing/sanitation leads to a proportionally lower risk of listeriosis."[18]

It is imperative for FSIS to determine the frequency of food-contact testing would be necessary to achieve its public-health goal to cut in half listeriosis illnesses by 2005. To this end, we recommend that FSIS use the model to evaluate a testing scenario based on the *Listeria* monitoring program, called the Pork Quality Improvement Process (PQIP), implemented in New Zealand.[19] (See attached.) PQIP's sampling program requires the following:

- Five samples every two weeks on non-product contact surfaces in the critical hygiene area;
- Five samples every two weeks on product-contact surfaces and surfaces from which product can be contaminated in the critical hygiene area; and
- Five product samples per month.

In addition, PQIP recommends the following:

- Three samples per month in the standard hygiene environment; and
- Discretionary sampling in the non-critical processing environment.

A vigorous, multi-tiered industry sampling regime, such as the PQIP program, increases the chance that *L. monocytogenes* will be detected before the product reaches consumers. Such

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[17] 66 Fed. Reg. at 12,620.

[18] *FSIS Draft Risk Assessment*, at 26.

[19] FSIS should use a single standard for test frequency because small plants are just as likely as large plants to experience conditions conducive to the growth of *Listeria* and are just as likely to experience post-lethality product contamination. Indeed, none of the industry's *Listeria* sampling guidelines discussed earlier establish sampling frequencies based on the number of firm employees. See *supra* note 9.

sampling not only protects consumer interests but is beneficial to producers as well. It provides an incentive for plants to implement the most effective intervention methods available, thus boosting development and use of pathogen identification and more effective processing equipment.

Conclusion

This summer's outbreak and recalls make clear that *L. monocytogenes* contamination of RTE deli meats remains a significant public-health threat. The comments FSIS receives on this risk assessment will be useful in future iterations of the model, but should not prevent the agency from finalizing its *L. monocytogenes* regulations to mandate increased industry testing for *Listeria*. CSPI urges FSIS to take that step without further delay, before yet another listeriosis outbreak claims more lives.

Sincerely,

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